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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/581,606

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Katsutoshi Yoshizato

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07/22/2009

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EXAMINER

MACAULEY, SHERIDAN R

ART UNIT

PAPER NUMBER

1651

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/581,606	<b>Applicant(s)</b> YOSHIZATO ET AL.	
	<b>Examiner</b> SHERIDAN R. MACAULEY	<b>Art Unit</b> 1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 2,3 and 9-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicant's response and amendment were received and entered on April 2, 2009 and April 29, 2009. All evidence and arguments have been fully considered. Claims 1-26 are pending. Claims 2, 3 and 9-26 are withdrawn due to a previous requirement for restriction. Claims 1 and 4-8 are examined on the merits in this office action.

### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 2, 2009 has been entered.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Reynolds et al. (Development, 1996, 122:3085-3094; document cited in prior action).

Art Unit: 1651

Claim 1 recites a hair growth method, which comprises: (a) preparing single cells from dermal papillae or dermal papilla cells and single cells from epidermal tissue; (b) mixing both of the single cells; and (c) transplanting the mixture of single cells to an incised epidermal site, thereby inducing a follicle from which a hair shaft is spontaneously generated. Claim 8 recites the hair growth method according to claim 1, wherein the dermal papilla single cells are cultured cells.

5. Reynolds teaches a hair growth method wherein a number of single cells from dermal papillae and single cells from epidermal tissue are prepared (p. 3088, par. 2), mixed together (p. 3088, par. 3), and transplanted into an incised epidermal site (p. 3088, par. 4-5; see also p. 3089, par. 2-4). Reynolds teaches that the dermal papilla cells are cultured cells (p. 3088, par. 2). The method of Reynolds would induce a follicle from which a hair shaft is generated.

6. Therefore, Reynolds anticipates all of the limitations of the cited claims.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1651

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1 and 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolowacz et al. (US 2003/0161815 A1) in view of Reynolds et al. (Development, 1996, 122:3085-3094; document cited in IDS). Claim 1 recites a hair growth method, which comprises: (a) preparing single cells from dermal papillae or dermal papilla cells and single cells from epidermal tissue; (b) mixing both of the single cells; and (c) transplanting the mixture of single cells to an incised epidermal site, thereby inducing a follicle from which a hair shaft is spontaneously generated. Claim 4 recites the hair growth method according to claim 1, wherein the incised epidermal site is formed by incision of a part of dermis and whole epidermal layer. Claims 5 and 6 recite the hair growth method according to claim 1, wherein the components are derived from human, specifically human scalp. Claim 7 recites the hair growth method according to claim 6,

Art Unit: 1651

wherein the incised epidermal site is formed in human scalp. Claim 8 recites the hair growth method according to claim 1, wherein the dermal papilla single cells are cultured cells.

11. Wolowacz teaches a hair growth method wherein a composition containing dermal papilla cells is transplanted to an incised epidermal site (abstract, p. 1, par. 13). Wolowacz teaches that the cells are delivered to the dermis (abstract); thus, the incision of Wolowacz is formed by incision of a whole epidermal layer and part of a dermal layer. Wolowacz teaches that the components are derived from human scalp, that the incised epidermal layer may be human scalp, and that the dermal papilla cells are cultured cells (p. 2, par. 19, 26). Wolowacz does not specifically teach the use of a composition containing epidermal tissue or epidermal cells in addition to the dermal papilla cells.

12. Reynolds teaches a hair growth method wherein a number of single cells from dermal papillae and single cells from epidermal tissue are prepared (p. 3088, par. 2), mixed together (p. 3088, par. 3), and transplanted into an incised epidermal site (p. 3088, par. 4-5; see also p. 3089, par. 2-4). Reynolds teaches that the dermal papilla cells are cultured cells (p. 3088, par. 2). The method of Reynolds would induce a follicle from which a hair shaft is generated.

13. At the time of the invention, a method comprising nearly all of the claimed elements was known, as taught by Wolowacz. Furthermore, it was known at the time of the invention that epidermal cells, along with dermal papilla cells, can be delivered to incised epidermal sites in hair growth methods that are similar to the claimed method, as taught by Reynolds. One of ordinary skill in the art would have been motivated to

Art Unit: 1651

combine these teachings because Reynolds teaches that epidermal cells can be used to revive the inductive status of dermal papilla cells (p. 3092, col. 2, par. 3).

Furthermore, Wolowacz teaches the desirability for the dermal papilla cells to be in close proximity to epidermal cells (p. 3, par. 27). One would thus have recognized the desirability to deliver epidermal cells as well as dermal papilla cells to an incised site in a hair growth method. One of ordinary skill in the art would have had a reasonable expectation of success in practicing the claimed method because Reynolds teaches the implantation of a range of tissues into incised epidermal sites (p. 3088, par. 2-4) and Wolowacz teaches that the method allows for precise and accurate delivery of cells to the patient (p. 1, par. 13). It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

14. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

### ***Response to Arguments***

15. Applicant's arguments filed April 2, 2009 have been fully considered but they are not persuasive. Applicant argues that Reynolds does not anticipate or render obvious the claimed invention because the reference does not teach the preparation and mixing of cells before transplantation. This is not found to be persuasive, however, because the reference clearly teaches that each cell type is isolated prepared (p. 3088, par. 2) before the cells are mixed together (p. 3088, par. 3) and transplanted into tissue.

Although applicant claims that the instant invention precludes the co-culturing of the cell

Art Unit: 1651

types, this element is not recited in the claims, which teach a method comprising the steps taught by Reynolds. Therefore, the reference anticipates the claimed invention.

16. Applicant further argues that the cited references do not render obvious the claimed invention because Wolowacz teaches away from transplanting epidermal cells by teaching the injection of papillae cells only. It is noted, however, that the reference does not teach that epidermal cells cannot be transplanted in such a method. Further, one of ordinary skill in the art would have been motivated to transplant a culture that included epidermal cells, such as that of Reynolds, because Reynolds teaches that epidermal cells can be used to revive the inductive status of dermal papilla cells, as discussed in detail above. Although applicant argues that one of ordinary skill in the art would not have a reasonable expectation of success in producing hair pores to be produced in the combined method, it is noted that both references teach that dermal papillae cells may be induced in such a way and that the proximity of these cells to epidermal cells would have enhanced their ability to do so. One of ordinary skill in the art would therefore reasonably expect to achieve the desired result. It would therefore have been obvious to one of ordinary skill in the art to combine the cited teachings to arrive at the claimed method.

17. Therefore, applicant's arguments have been fully considered, but they have not been found to be persuasive.

### ***Conclusion***

No claims are allowed.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/  
Primary Examiner, Art Unit 1651

SRM